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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,233	06/27/2003	Imtiaz Chaudry	0040964-0002	8210

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/609,233	CHAUDRY, IMTIAZ	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *6-11,17-20,22-24,33,35-37 and 41-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,12-16,21,25-32,34,38-40 and 51-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/27/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of specific species for initial prosecution in the reply filed on 12/07/05 is acknowledged.

Accordingly, claims 6-11, 17-20, 22-24, 33, 35-37, 41-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species.

Receipt of Amendments filed on 12/07/05 is also acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 12-14, 16, 21, 25-32, 38-40, 51-61, 65-67 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al (5,554,610).

Williams teaches a **method for the treatment** of disorders associated with **pulmonary hypertension** comprising administering to a mammal an effective amount of a vasodilator. The formulations can treat primary and secondary pulmonary hypertensions (col. 2, lines 1-6). The administration is preferably **through inhalation**. **Unit doses** comprising 0.01 to 50 mg and preferably from 0.1 to 10 mg of the compound are normally administered one to 4 times a day. The compositions are

prepared by admixture and can be in a solution or **suspension** form (col. 2, lines 16-48, 60-67). One preferred composition comprises in an **aqueous suspension** form, additives such as suspending agents, preservatives, carriers and buffers. The said agents include **propylene glycol**, **ethyl alcohol,** etc. The compositions for administration to the respiratory tract are presented as **snuff** or an aerosol or solution for a **nebulizer** or as a microfine powder for insufflation, alone or in combination with an inert carrier. In other preparations, such as for parenteral administration, the fluid unit dose forms are prepared containing the compound and a **sterile** vehicle, undergo **filter sterilization** and filled into a vial. The compositions are typically accompanied by written or printed directions for use (see col. 3, lines 1-66).

Williams also discloses that suitable vasodilators include **calcium channel blockers** such as **nifedipine** (col. 4, lines 20-21). A particularly favored pharmaceutically acceptable composition is an inhalation composition, suitably in unit dosage form (col. 4, lines 37-40).

Although Williams does not specifically disclose the amount of active agents in mg/ml, this is inherently disclosed, because the dose is disclosed and the unit dosages in liquid form are disclosed.

Claims 1-2, 12-16, 21, 25-30, 32, 34, 38-40, 51-52, 54, 57-61, 66-67 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwarz (US 20010031738).

Schwarz teaches methods and formulations for treatment of pulmonary hypertension. Pulmonary hypertension can be a primary or a secondary hypertension

([0004] and [0005]). The compounds useful for treatment include calcium channel blockers such as **nifedipine or diltiazem** and **digoxin** (see [0008] and [0036]). The formulations may be administered via parenteral, buccal, or other routes. Most preferred is direct administration to the lungs such as by the **inhalation** of respirable aerosol particles comprising the active agent (see [0038]). A suitable carrier includes **sterile saline solution or sterile water** ([0039]). The compounds are typically admixed with the carriers and formulated into **unit dosages** comprising from 0.1 to 0.5% or 95 or 99% by weight of the carrier based on the active compound (see [0040]). The formulations also may contain additives such as buffers like **sodium citrate**, preservatives, etc, where the formulation is placed in a **vial** designed for multi-dose units ([0041] and [0042]). The formulation may be in an **aqueous suspension** form containing a **predetermined** amount of active agent and presented in **discrete units**. In general, the formulations are prepared by uniformly and intimately admixing the active agent with liquid carrier ([0043]).

Schwarz also discloses that the aerosol **suspensions** can be aerosolized by a metered dose inhaler ([0049]) or with a pressure-driven **aerosol nebulizer** or an **ultrasonic nebulizer**. The suitable carrier is typically water and most preferably **sterile** water, and preferably made **isotonic**. Optional preservatives, buffering agents and surfactants are included (see [0051]). The doses of the active compounds may be provided as **one or several prepackaged units** (see [0059]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 62-64 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al (5,554,610).

Wiliams, discussed above, does not anticipate the amounts of suspending agent in the formulation or amount of formulations in each vial. However the said limitations are obvious to one of ordinary skill in the art. Firstly, the concentration range of suspending agent recited in claim 64 is form 0.01 to 90%, which by itself is very broad and almost certainly covers all options. Secondly, optimization of concentration ranges are routine practice for those of ordinary skill in the art and not support for patentability. Furthermore the amount of formulation in a unit dose vial is dependent on the active agent, the use and similar limitations and not considered a novelty.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

Mina Haghighatian
March 16, 2006